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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/305,084

05/04/1999

Robert J. Schneider

5914-080-999

1583

20583

7590

02/23/2005

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/305,084

Applicant(s)

SCHNEIDER ET AL.

Examiner

Karen A Canella

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 33-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-32 have been canceled. Claims 33-42 have been added and are under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a previous action.

The rejection of claims 37-40 and 42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

Applicant argues that the art recognizes what a "small molecule inhibitor of ETB receptor" is and has provided references to support this position. This has been considered but not found persuasive. While "small molecule inhibitors" are recognized in the art as such, the art does not provide a limiting definition of said "small" molecule inhibitors that would serve to discern molecules which were not encompassed by the claims.

Claims 33-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the development or progression of melanoma comprising administering to a patient in need thereof a compound that is an endothelin B receptor specific antagonists, does not reasonably provide enablement for a method of preventing the initiation of melanoma comprising administering to a patient in need thereof a compound that is an endothelin B receptor specific antagonists.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The instant claims are drawn in part to a method of preventing the initiation of melanoma comprising administering to a patient in need thereof a compound that is an endothelin B receptor specific antagonist. The art teaches that the initiation of cancer is a mutational event (the abstract of Ramel et al, Environmental Science Research, 1984, Vol. 41, pp. 97-112). The specification teaches that ETB receptor antagonists inhibit the early events associated with melanoma development. However, the specification does not teach how to use the instant methods to inhibit the initiation of melanoma, because there is no nexus between the administration of the ETB antagonists and the prevention or reversal of a mutational event such

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that the primary initiation event in melanoma is prevented. Further, the specification does not teach how to identify a "patient in need thereof" wherein said patient is treated with the ETB antagonists before the mutational event that leads to initiation of melanoma, because said patients would be without atypical lesions because initiation, by definition, precedes progression.

Claims 33-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn in part to a method of preventing the initiation of melanoma comprising administering to a patient in need thereof a compound that is an endothelin B receptor specific antagonist. The art teaches that the initiation of cancer is a mutational event (the abstract of Ramel et al, Environmental Science Research, 1984, Vol. 41, pp. 97-112). The specification teaches that ETB receptor antagonists inhibit the early events associated with melanoma development. However, there is no mechanistic nexus between inhibiting ET-1 activity at the ETB receptor and preventing a mutational event such that the primary initiation event in melanoma is prevented. One of skill in the art, upon reading of the originally filed specification would reasonably conclude that applicant was not in possession of a method of preventing melanoma initiation.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

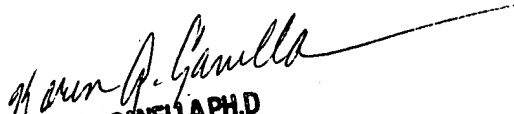
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

2/22/2005


KARENA CANELLA PH.D
PRIMARY EXAMINER